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**Smith**

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(54) **OFF-WALL ELECTRODE DEVICE AND METHODS FOR NERVE MODULATION**


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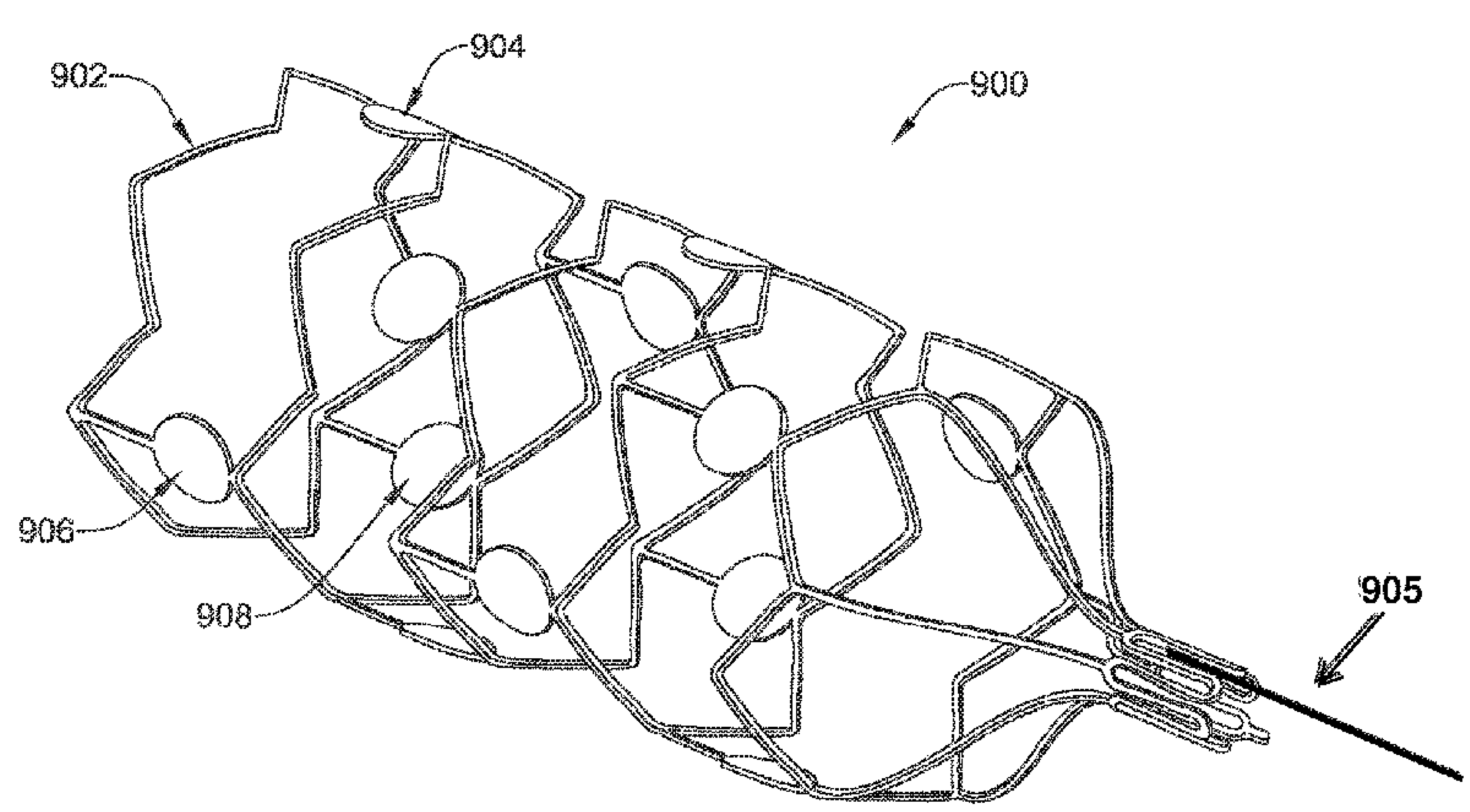
(57) **ABSTRACT**


Systems for nerve modulation through the wall of a blood vessel are disclosed. An example system for nerve modulation may include an elongate member extending along a central elongate axis and having a proximal end and a distal end. The elongate member may have a radially expandable member disposed proximate the distal end. A tubular sheath may be cooperatively engaged with the expandable member such that the expandable member is collapsed when in the sheath and can expand when moved distally relative to and past a distal end of the sheath. The expandable member may include a plurality of electrodes and a plurality of spacer struts. Each spacer strut may be configured such that when the self-expanding member is in an expanded state the spacer strut extends out radially further than the electrodes from the central elongate axis.


**20 Claims, 14 Drawing Sheets**



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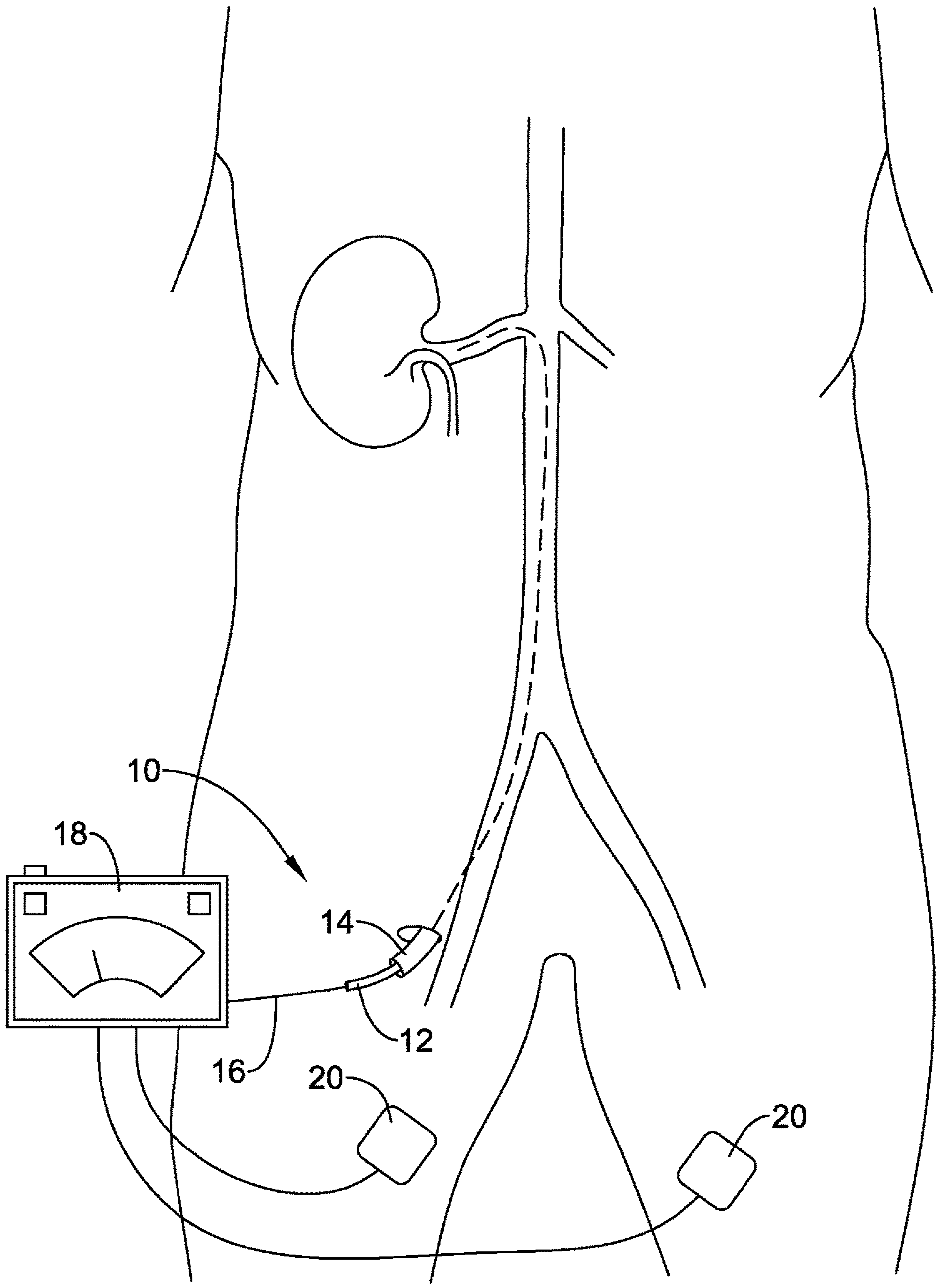


*Figure 1*

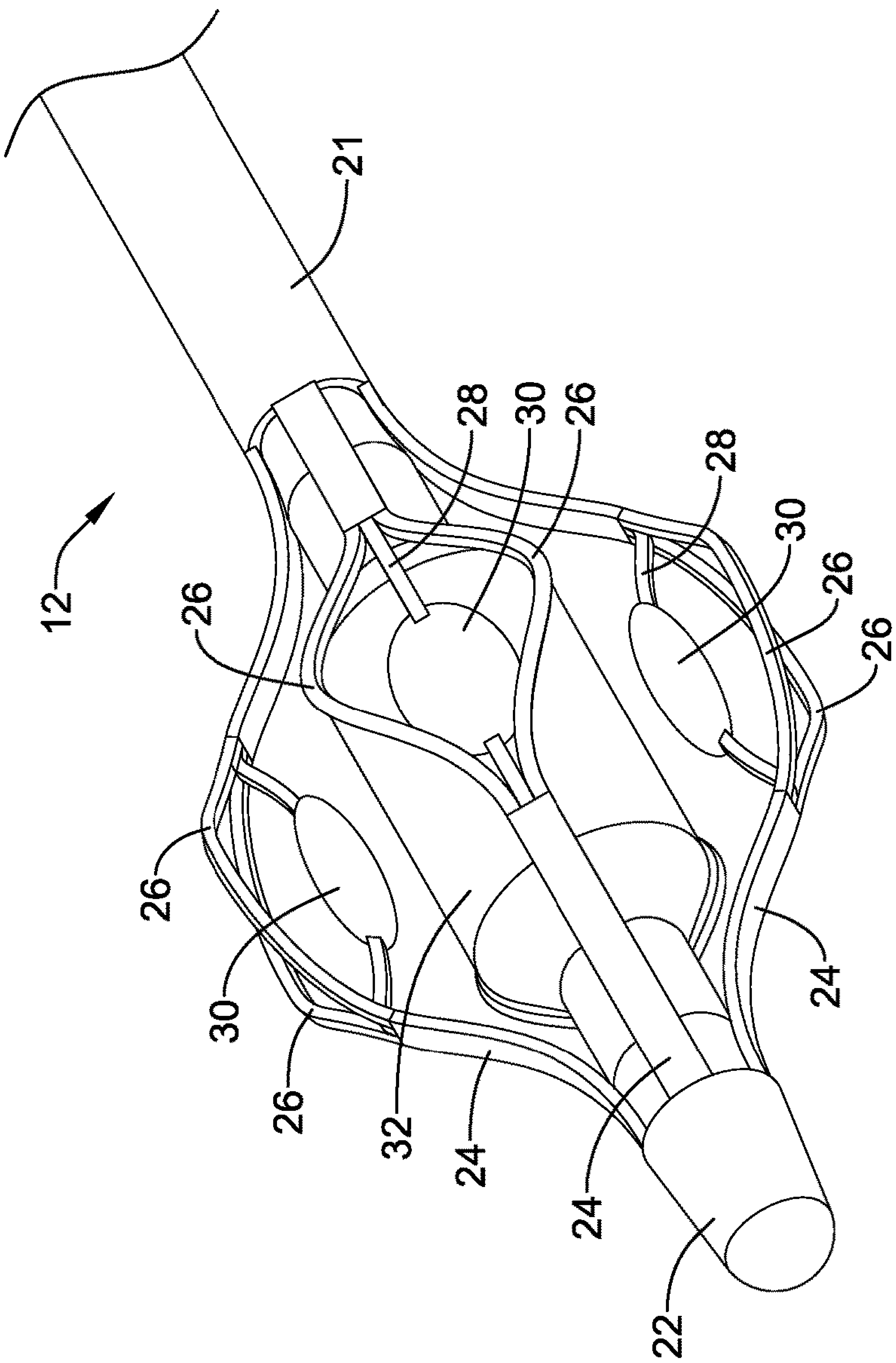


Figure 2

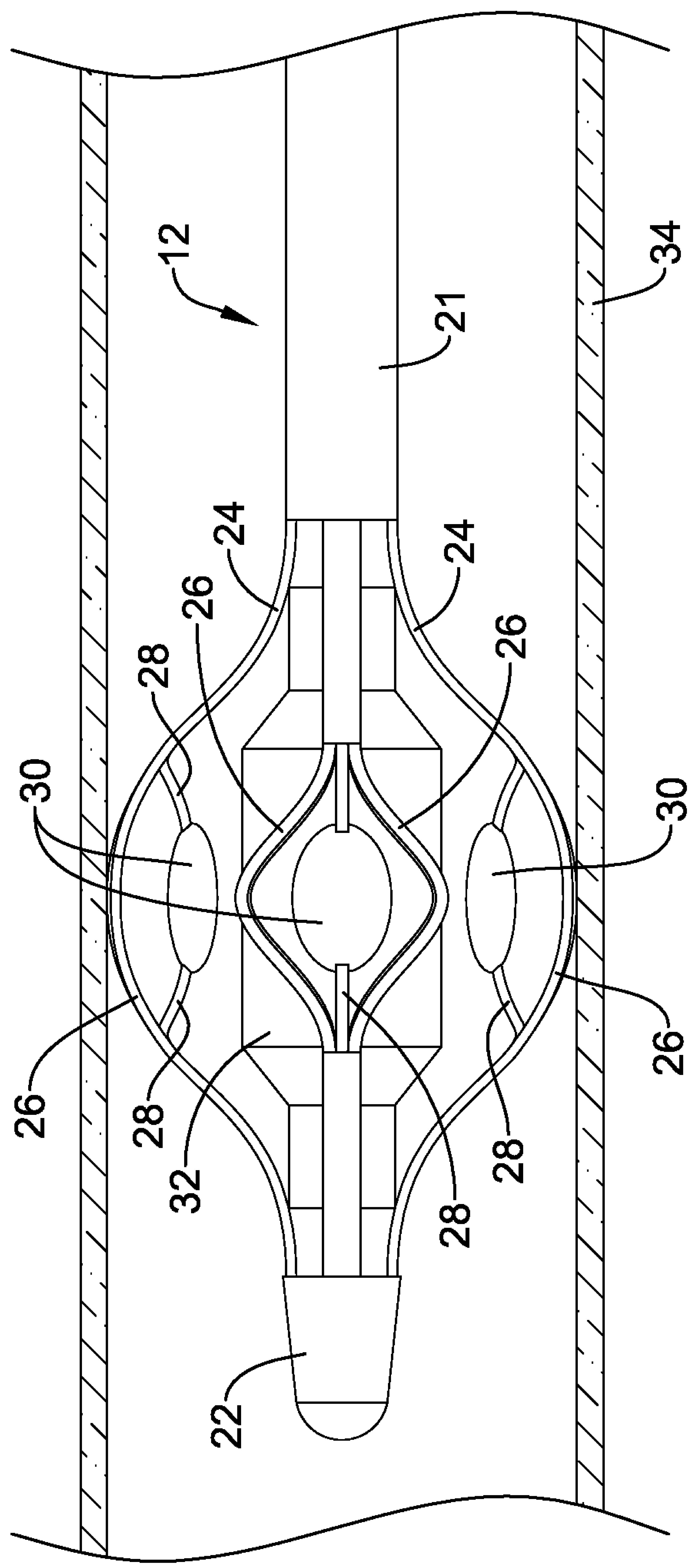


Figure 3A

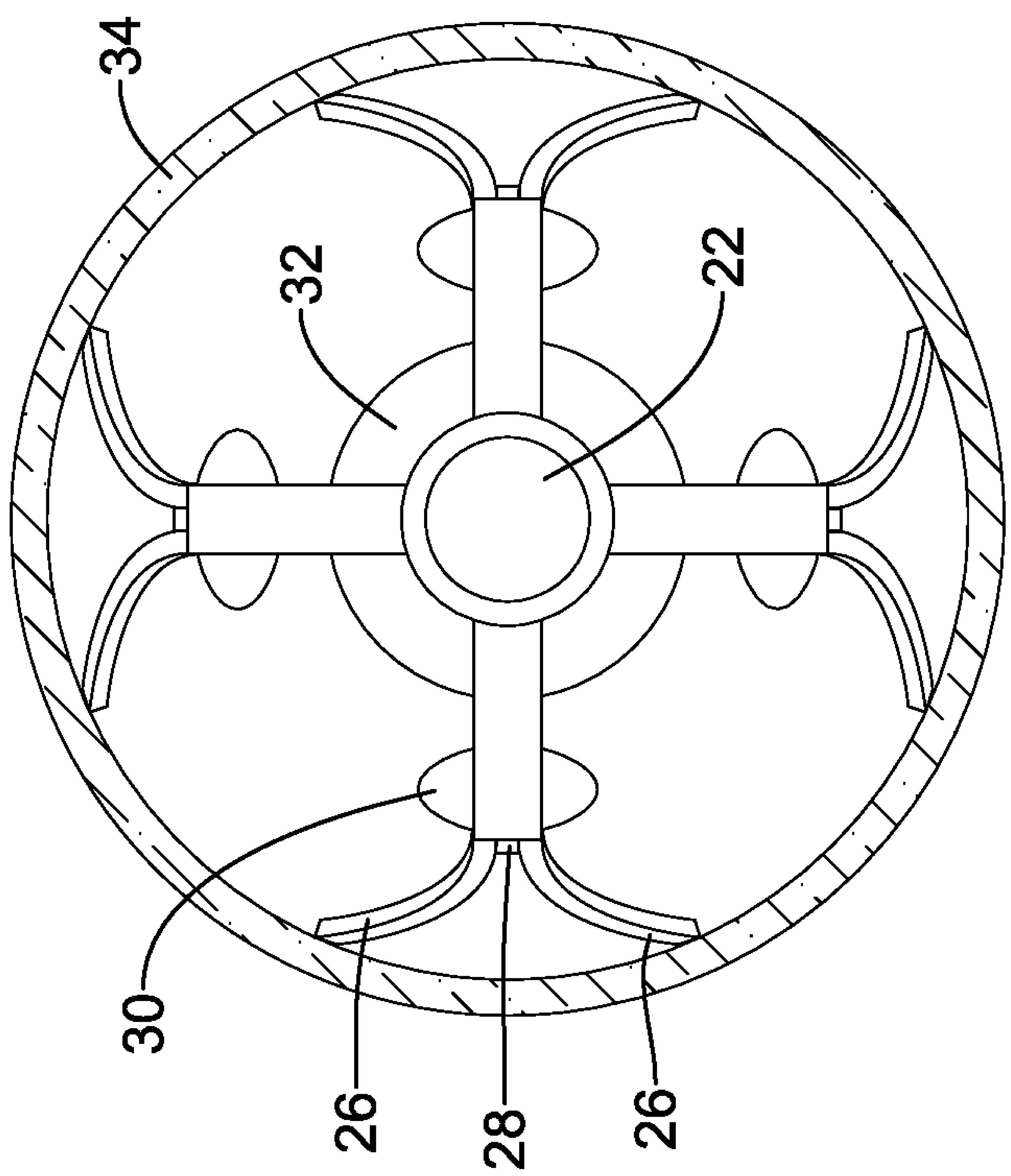


Figure 3B

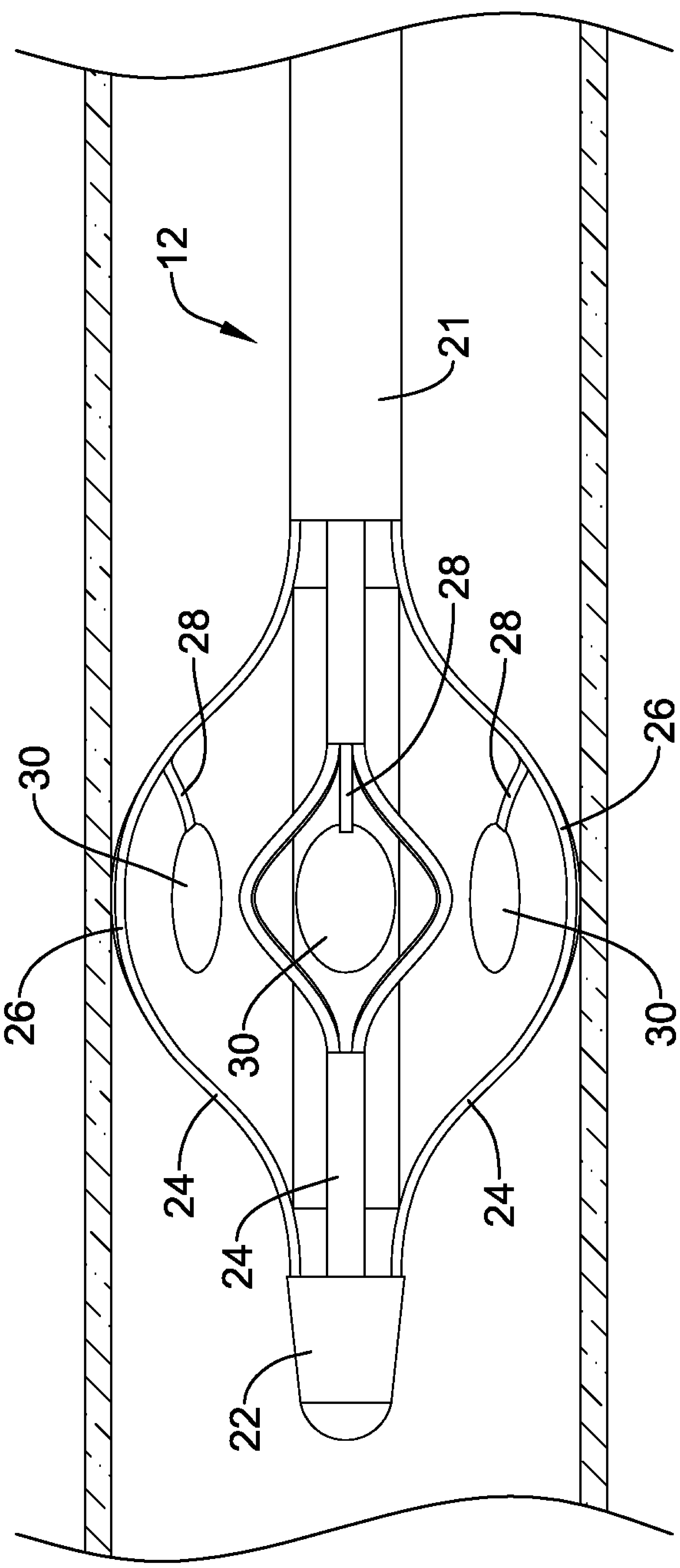


Figure 4

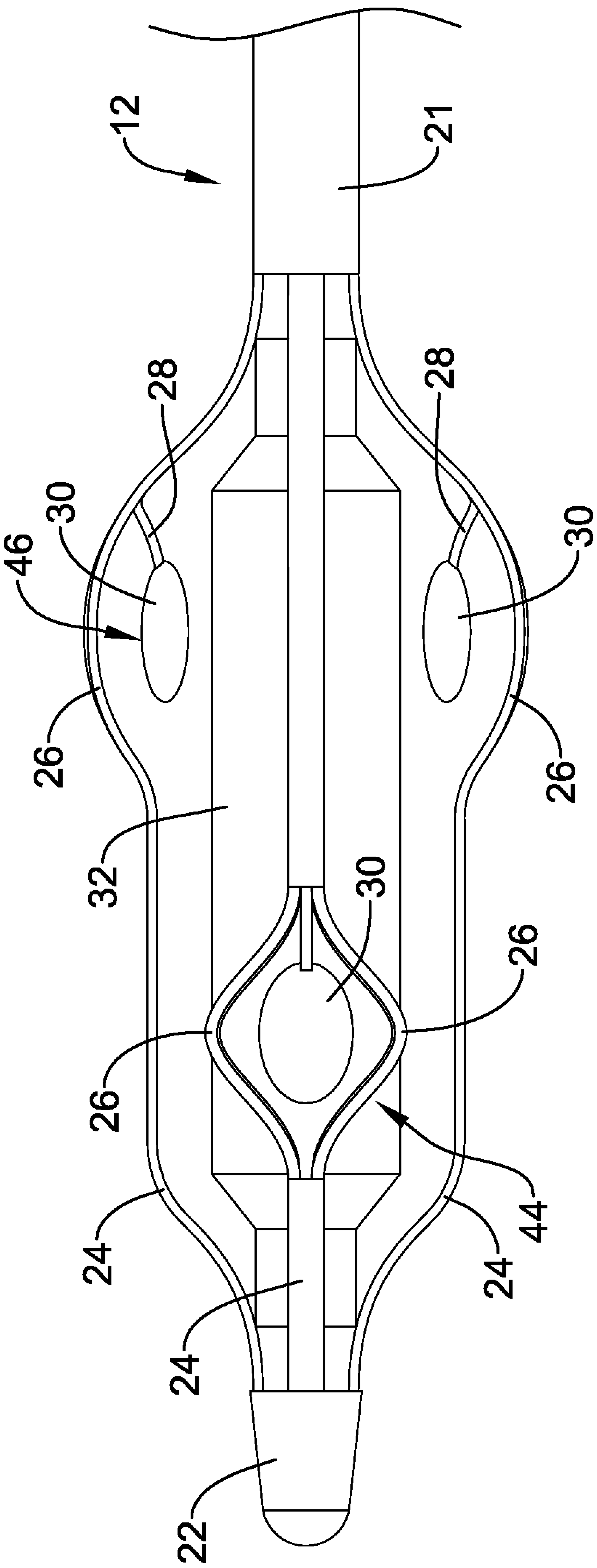


Figure 5

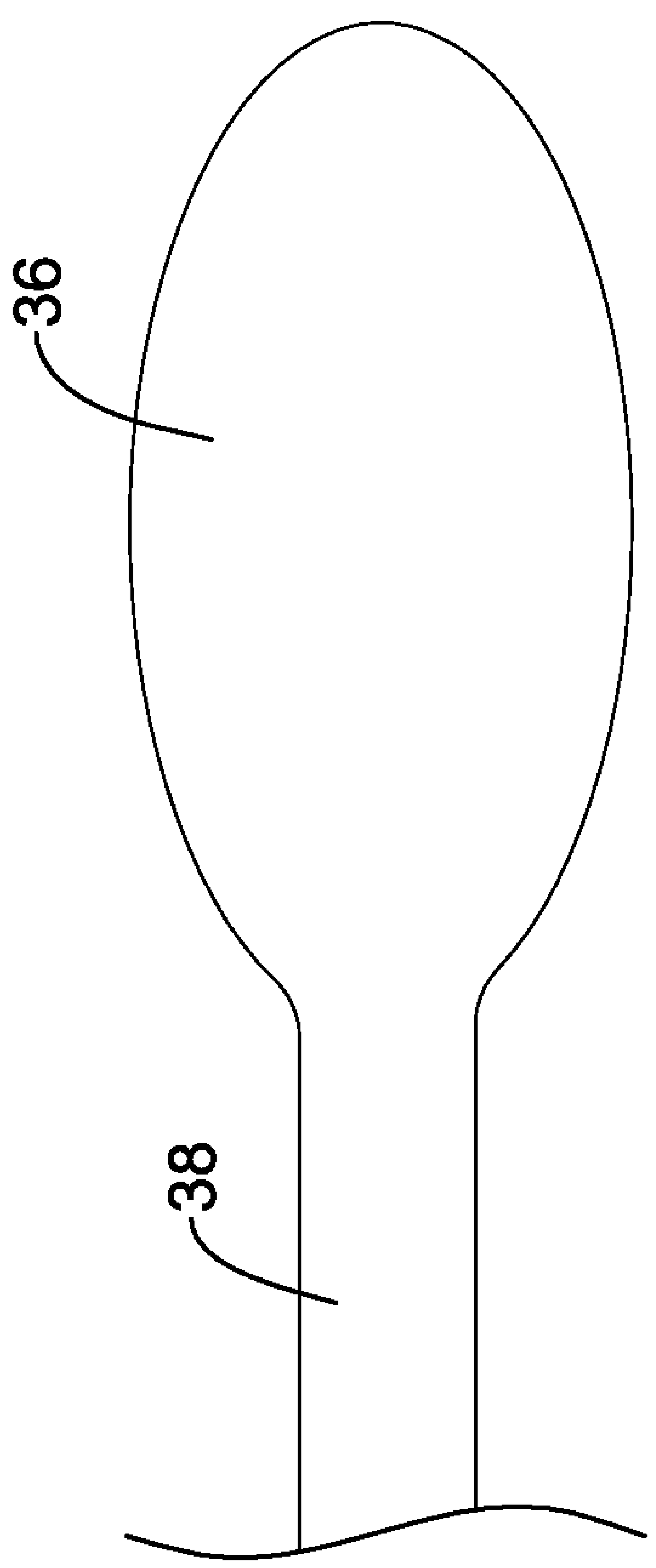


Figure 6A

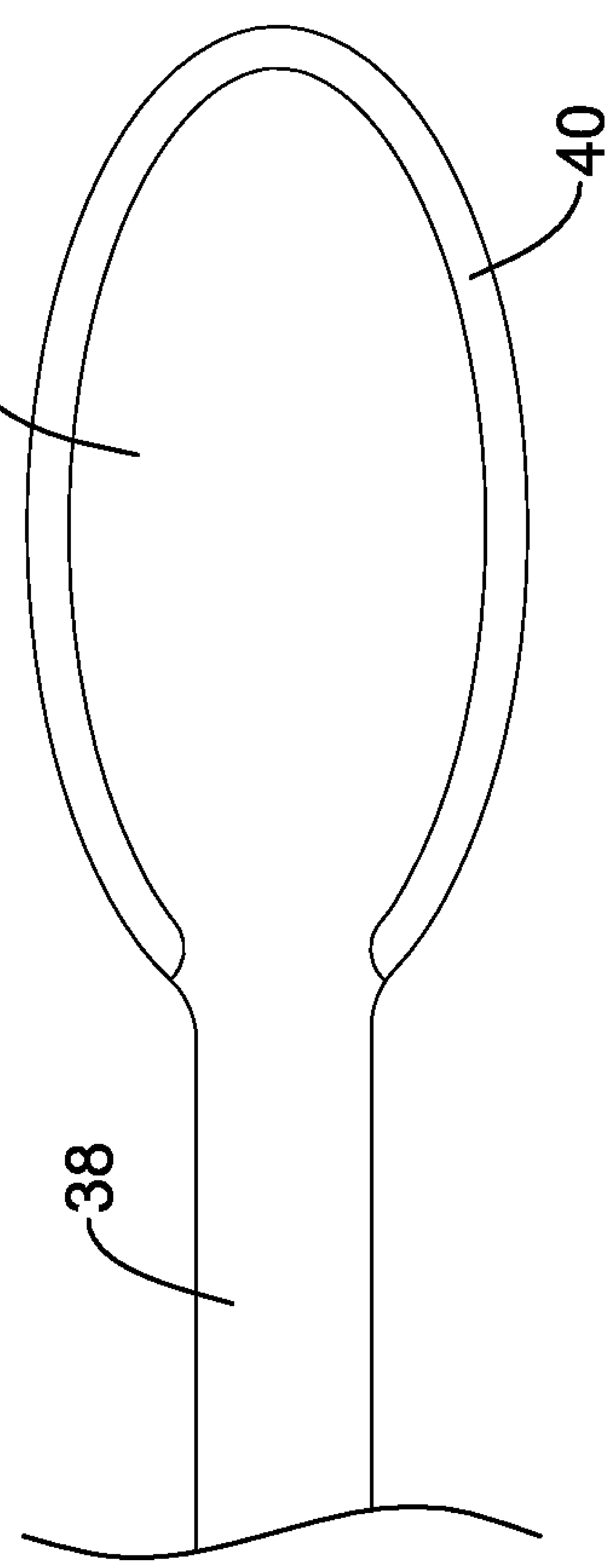


*Figure 6B*

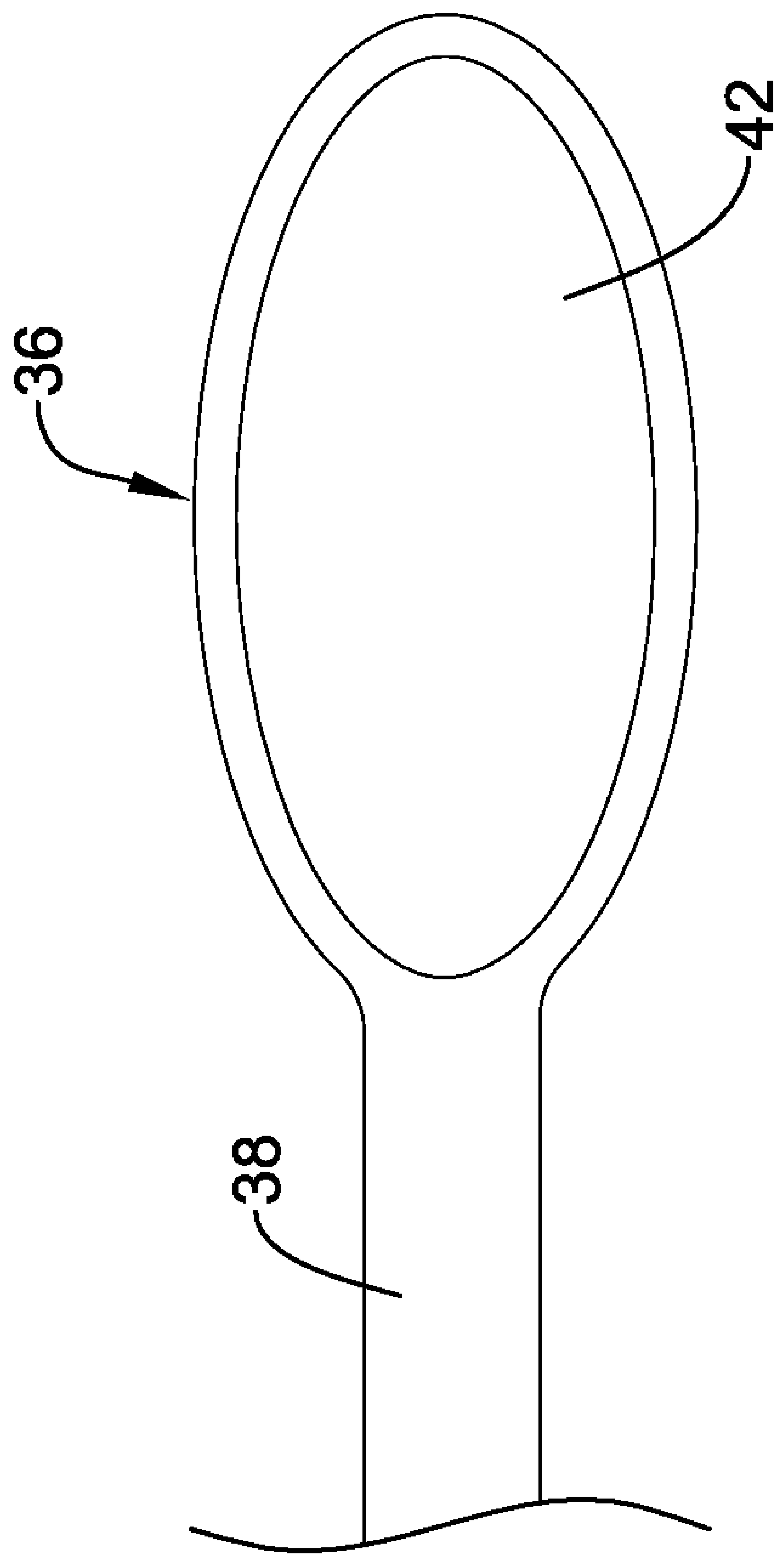


Figure 6C

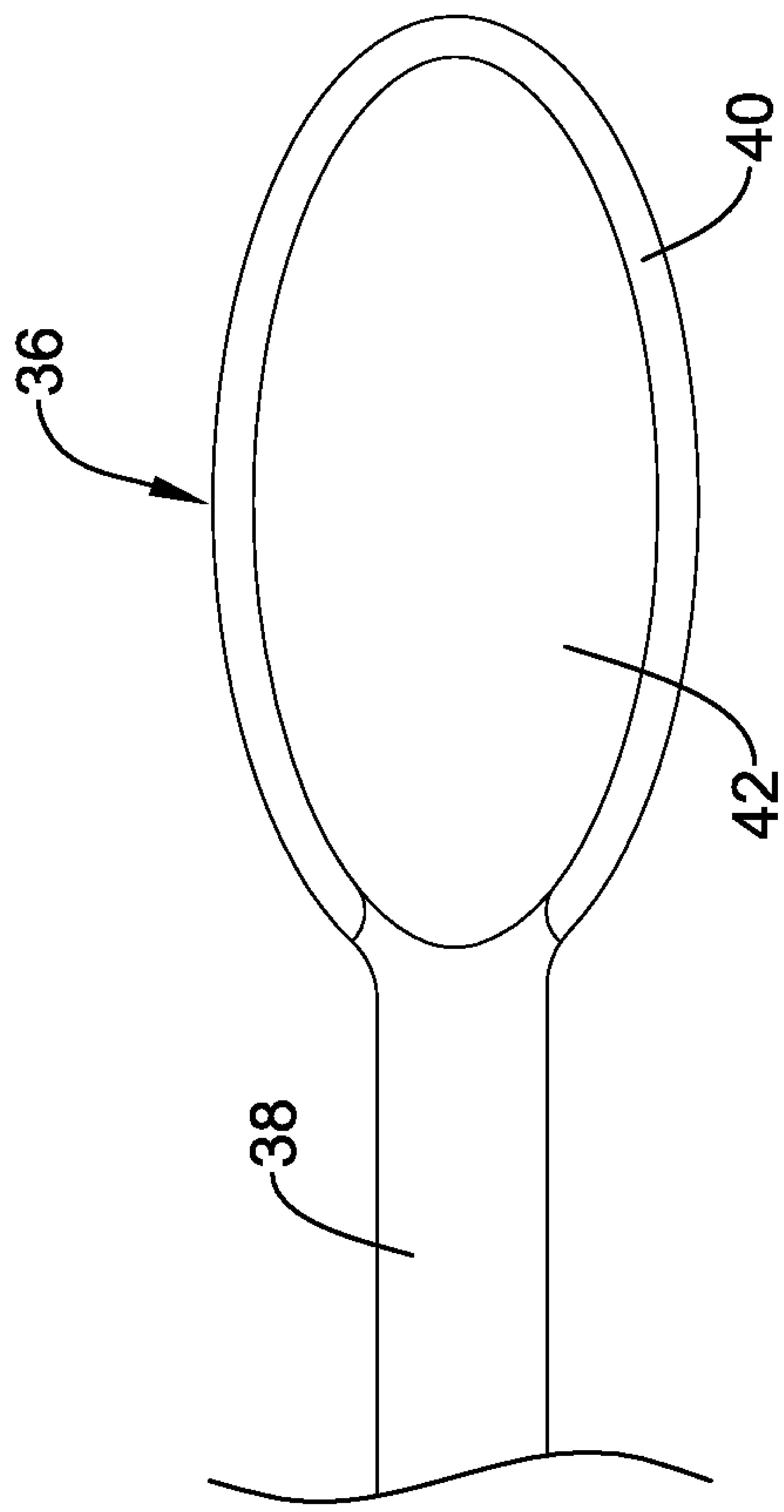


Figure 6D

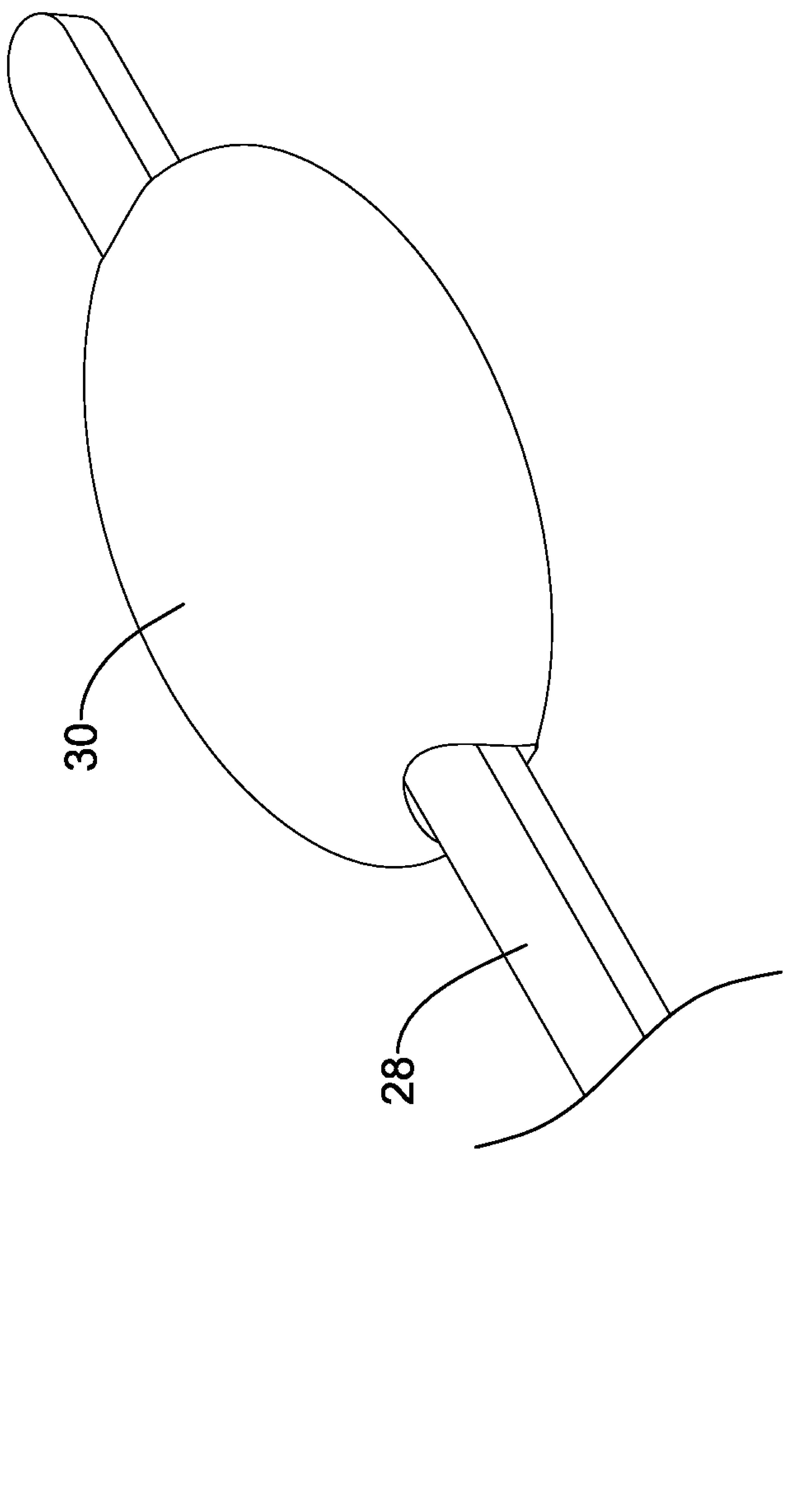


Figure 7

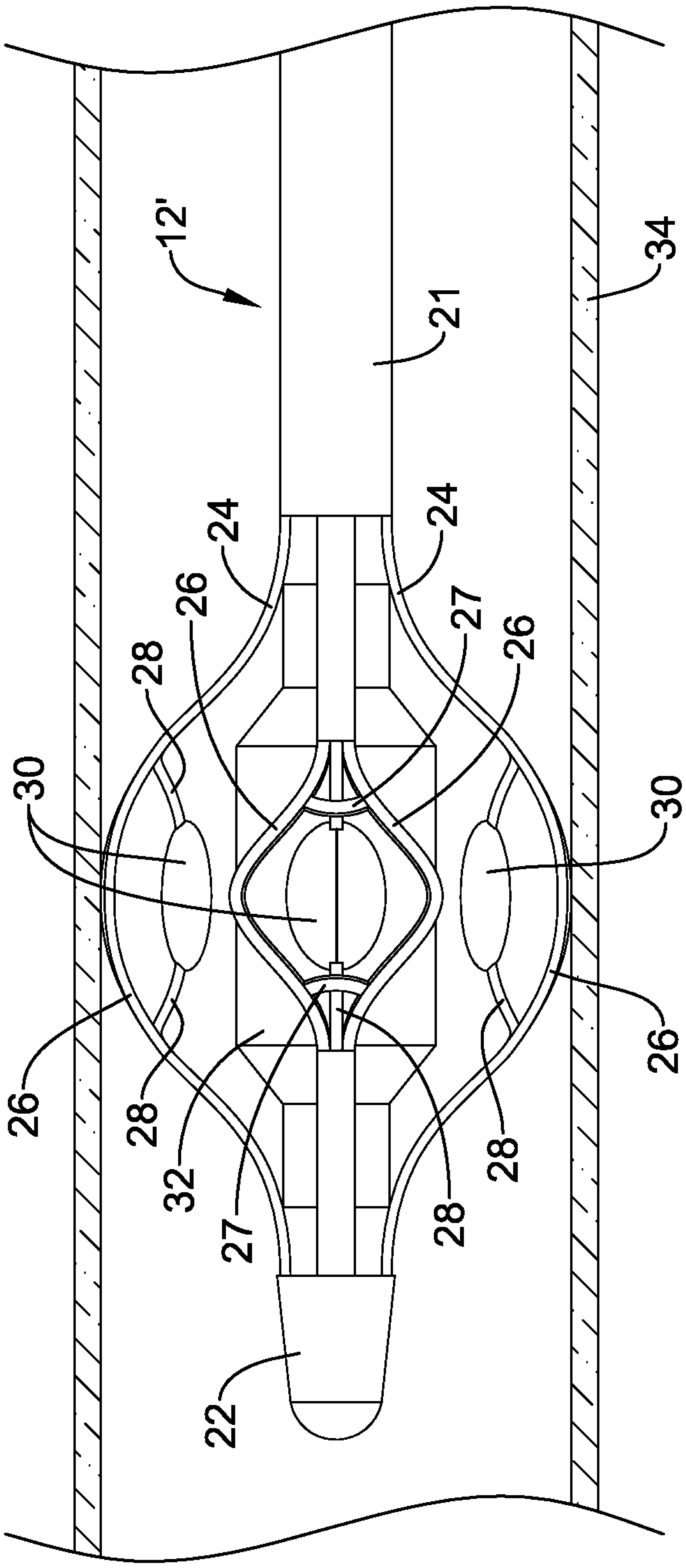


Figure 8A

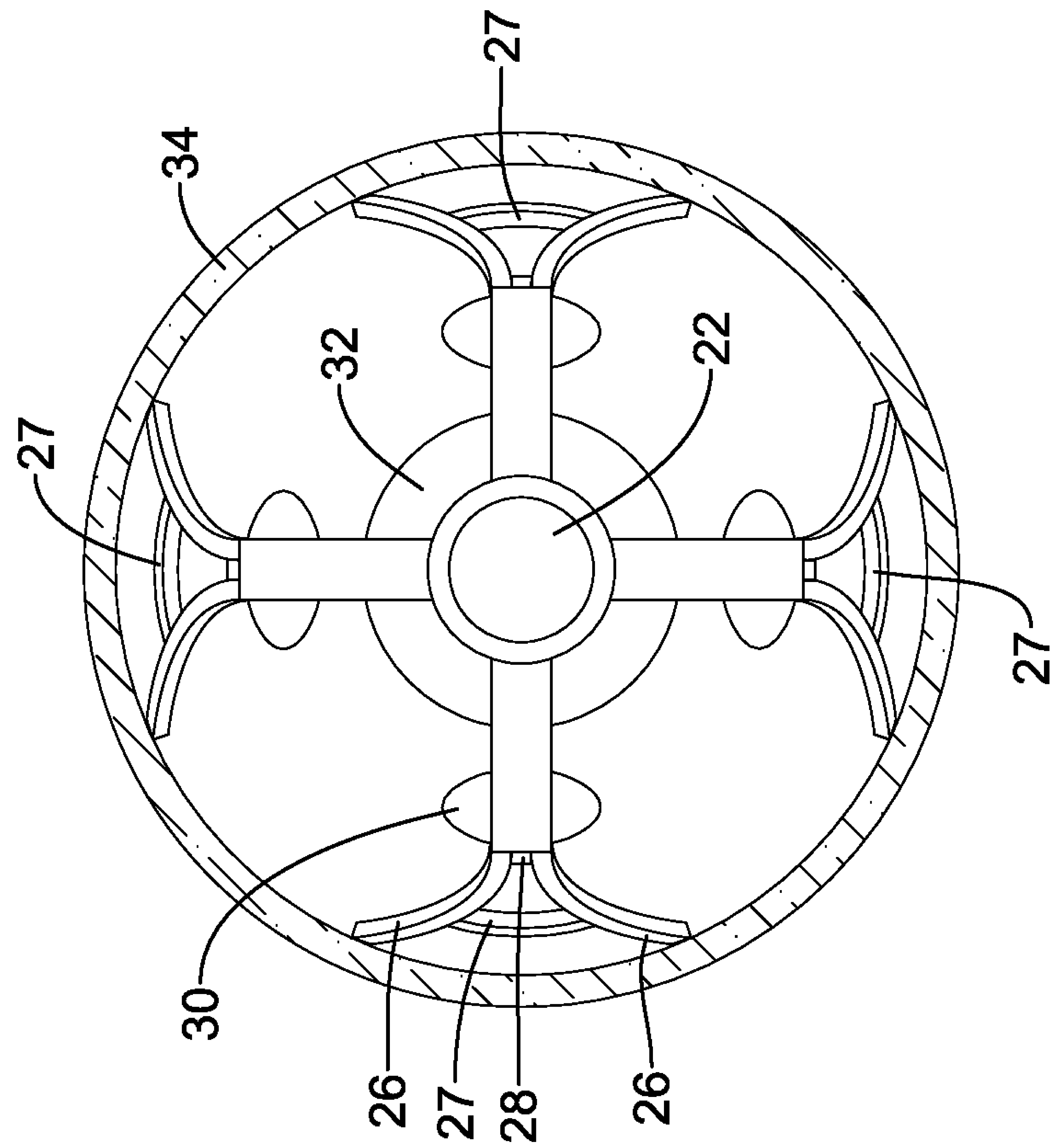


Figure 8B

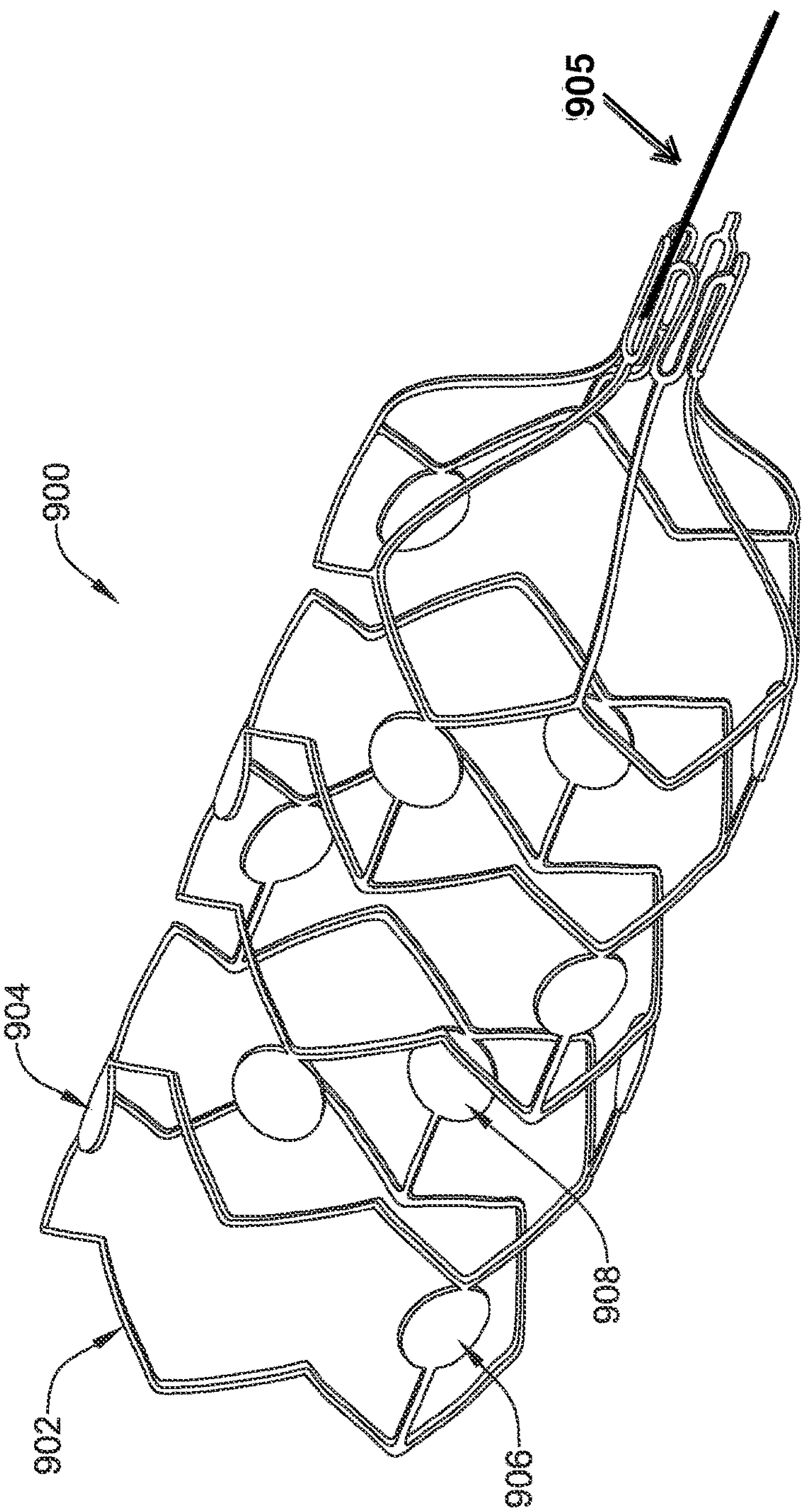


Figure 9

# OFF-WALL ELECTRODE DEVICE AND METHODS FOR NERVE MODULATION

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. § 119 to U.S. Provisional Application Ser. No. 61/605,599, filed Mar. 1, 2012 and to U.S. Provisional Application Ser. No. 61/545,912, filed Oct. 11, 2011, both of which are herein incorporated by reference.

## TECHNICAL FIELD

The present invention relates to methods and apparatuses for modulation of nerves through the walls of blood vessels. Such modulation may include ablation of nerve tissue or other modulation technique.

## BACKGROUND

Certain treatments require the temporary or permanent interruption or modification of select nerve function. One example treatment is renal nerve ablation which is sometimes used to treat conditions related to congestive heart failure. The kidneys produce a sympathetic response to congestive heart failure, which, among other effects, increases the undesired retention of water and/or sodium. Ablating some of the nerves running to the kidneys may reduce or eliminate this sympathetic function, which may provide a corresponding reduction in the associated undesired symptoms.

Many nerves (and nervous tissue such as brain tissue), including renal nerves, run along the walls of or in close proximity to blood vessels and thus can be accessed intravascularly through the walls of the blood vessels. In some instances, it may be desirable to ablate perivascular renal nerves using a radio frequency (RF) electrode. However, such a treatment may result in thermal injury to the vessel wall at the electrode and other undesirable side effects such as, but not limited to, blood damage, clotting and/or protein fouling of the electrode. Increased cooling in the region of the nerve ablation may reduce such undesirable side effects.

Therefore, there remains room for improvement and/or alternatives in providing for systems and methods for intravascular nerve modulation.

## SUMMARY

The disclosure is directed to several alternative designs, materials and methods of manufacturing medical device structures and assemblies.

Accordingly, some embodiments pertain to a system for nerve modulation through the wall of a blood vessel, comprising an elongate member extending along a central elongate axis and having a proximal end and a distal end, the elongate member having a radially expandable member disposed proximate the distal end, and a tubular sheath cooperatively engaged with the expandable member such that the expandable member is not expanded when in the sheath and can expand when moved out of the sheath, the expandable member comprising a plurality of electrodes and a plurality of spacer struts, each spacer strut configured such that when the expandable member is in an expanded state the spacer strut extends out radially further than the electrodes from the central elongate axis. The elongate member may further comprise an expandable blood vessel occluder disposed under the plurality of electrodes, the occluder having an expanded state such that when the occluder is in the expanded state and the self-expanding member is in the expanded state, there is a gap between each of the plurality of electrodes and the occluder. The expandable member may be self-expanding, being biased to an expanded state or may be balloon-expandable or expandable using some other suitable mechanical means. If the expandable member is balloon-expandable, it may be biased to a non-expanded state. The expandable member may comprise a pair of spacer struts for each electrode, wherein each pair of spacer struts defines a gap in which the corresponding electrode is located. The expandable member may comprise a first set of electrodes and spacer struts and a second set of electrodes and spacer struts and wherein the first set is disposed at a different axial location relative to the second set. In such a case, it may be that none of the electrodes in the first set are at the same radial position as any of the electrodes in the second set. The expandable member may comprise a plurality of sets, each set comprising an electrode and a spacer strut, each set being electrically isolated from the other sets. In one of such sets, an electrode is disposed on an electrode strut, the electrode strut having a free end and a joined end, the joined end of the electrode strut being joined to the spacer strut. Such a set may be made by forming the electrode and the electrode strut from the same precursor to create a monolithic strut/electrode assembly. The electrode may have a perimeter and a first material and further comprising a layer of a second conductive material disposed on a surface of the electrode and wherein the layer does not extend to the perimeter. The electrode may have a first side, a second side and a perimeter therebetween, and further comprising an insulating material on the perimeter. The system may be configured such that when the expandable member is in an expanded state in the blood vessel, there is a shortest path between each electrode and the vessel wall and wherein no element of the system is disposed in the shortest paths.

Some embodiments pertain to a system for nerve modulation through the wall of a blood vessel, comprising an elongate member extending along a central elongate axis and having a proximal end and a distal end, the elongate member having a radially expandable member disposed proximate the distal end and an expandable occlusive member disposed beneath the radially expandable member, and a tubular sheath cooperatively engaged with the expandable member such that the expandable member is not expanded when in the sheath and can expand when moved distally out of the sheath, the expandable member comprising a plurality of electrodes and a plurality of spacer struts, each spacer strut configured such that when the expandable member is in an expanded state the spacer strut extends out radially further than the electrodes from the central elongate axis. The expandable member may have an expanded state and a maximum diameter in the expanded state and wherein the expandable occlusive member is expandable to a diameter of between 40% and 60% of the maximum diameter of the self-expanding member. The expandable occlusive member may have an expanded state such that when the self-expanding member is in the expanded state and the expandable occlusive member is in the expanded state, the electrodes are spaced away from the expandable occlusive member. The expandable occlusive device may include an inflatable balloon. The expandable occlusive device may comprise a self-expanding structure covered with a membrane substantially impervious to blood flow, the self-ex-

panding structure defining a central cavity and the membrane configured to prevent significant blood flow through the central cavity.

Some embodiments pertain to a method of manufacturing a system for nerve modulation, comprising the steps of providing a first elongate flexible member, providing a resilient tubular member having an outer surface, a central cavity and proximal and distal ends, forming spacer struts in the resilient tubular member, fixing the elongate flexible member within the central cavity by joining the proximal end of the resilient tubular member to the elongate flexible member; and subsequent to the step of fixing, forming two cuts in the resilient tubular member, each cut extending from the proximal end to the distal end and from the outer surface to the central cavity along the entire length from the proximal end to the distal end. The method may include the step of forming two cuts, fixing a tubular non-conductive layer over the proximal end of the resilient tubular member, the layer joined to the resilient tubular member and to the first elongate flexible member.

Some embodiments pertain to a system that further includes one or more boundary layer control elements. Such a boundary layer control element may be a trip strut spaced from the vessel wall and downstream of the electrode. The trip strut may cause the blood flow to be more turbulent, thereby increasing heat transfer between the blood and the vessel wall.

Some embodiments pertain to a system where the electrodes have a non-conductive or inert side that faces or is against the vessel wall and an active or conductive side that faces radially inwardly.

The above summary of some example embodiments is not intended to describe each disclosed embodiment or every implementation of the invention.

## BRIEF DESCRIPTION OF THE DRAWINGS

The invention may be more completely understood in consideration of the following detailed description of various embodiments in connection with the accompanying drawings, in which:

FIG. **1** is a schematic view illustrating a renal nerve modulation system in situ.

FIG. **2** illustrates a distal end of an illustrative renal nerve modulation system.

FIG. **3**A is a side view of the illustrative renal nerve modulation system of FIG. **2** in a blood vessel.

FIG. **3**B is an end view of the illustrative renal nerve modulation system of FIG. **2** in a blood vessel.

FIG. **4** is a side view of an illustrative renal nerve modulation system in a blood vessel.

FIG. **5** is a side view of an illustrative renal nerve modulation system.

FIG. **6**A is a view of an illustrative electrode/strut unit.

FIG. **6**B is a view of an illustrative electrode/strut unit.

FIG. **6**C is a view of an illustrative electrode/strut unit.

FIG. **6**D is a view of an illustrative electrode/strut unit.

FIG. **7** is a view of an illustrative electrode on a strut.

FIG. **8**A is a side view of an illustrative renal nerve modulation system in a blood vessel.

FIG. **8**B is an end view of the illustrative renal nerve modulation system of FIG. **8**B in a blood vessel.

FIG. **9** is an isometric view of the distal portions of an illustrative renal nerve modulation system.

While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in



detail. It should be understood, however, that the intention is not to limit aspects of the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention.

## DETAILED DESCRIPTION

For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

All numeric values are herein assumed to be modified by the term “about”, whether or not explicitly indicated. The term “about” generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the term “about” may be indicative as including numbers that are rounded to the nearest significant figure.

The recitation of numerical ranges by endpoints includes all numbers within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

Although some suitable dimensions ranges and/or values pertaining to various components, features and/or specifications are disclosed, one of skill in the art, incited by the present disclosure, would understand desired dimensions, ranges and/or values may deviate from those expressly disclosed.

As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise.

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The detailed description and the drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention. The illustrative embodiments depicted are intended only as exemplary. Selected features of any illustrative embodiment may be incorporated into an additional embodiment unless clearly stated to the contrary.

While the devices and methods described herein are discussed relative to renal nerve modulation, it is contemplated that the devices and methods may be used in other applications where nerve modulation and/or ablation are desired.

In some instances, it may be desirable to ablate perivascular renal nerves with deep target tissue heating. However, as energy passes from an electrode to the desired treatment region the energy may heat the fluid and tissue as it passes. As more energy is used, higher temperatures in the surrounding tissues may be achieved, but may result in some negative side effects, such as, but not limited to thermal injury to the vessel wall, blood damage, clotting and/or protein fouling of the electrode. Positioning the electrode away from the vessel wall may provide some degree of passive cooling by allowing blood to flow past the electrode. However, it may be desirable to provide an increased level of cooling. In some instances, a partial occlusion catheter may be used to partially occlude an artery or vessel during nerve ablation. The partial occlusion catheter may increase the velocity of blood flow in a region proximate the desired treatment area while minimally affecting the volume of blood passing, if at all. The increased velocity of blood flow may increase the convective cooling of the blood and tissue surrounding the treatment area and reducing artery wall thermal injury, blood damage, and/or clotting. The renal nerve modulation systems described herein may include other mechanisms to improve convective heat transfer, such as, but not limited to directing flow patterns with surfaces, flushing fluid from a guide catheter or other lumen, or infusing cool fluid.

FIG. **1** is a schematic view of an illustrative renal nerve modulation assembly **10** in situ. Assembly **10** may include one or more conductive element(s) **16** for providing power to renal ablation system **12** disposed within a sheath **14**, the details of which can be better seen in subsequent figures. Alternatively, the sheath **14** may take the form of a guide catheter. A proximal end of conductive element **16** may be connected to a control and power element **18**, which supplies the necessary electrical energy to activate the one or more electrodes at or near a distal end of the renal ablation system **12**. In some instances, return electrode patches **20** may be supplied on the legs or at another conventional location on the patient's body to complete the circuit. The control and power element **18** may include monitoring elements to monitor parameters such as power, temperature, voltage, pulse size and/or shape and other suitable parameters as well as suitable controls for performing the desired procedure. In some instances, the power element **18** may control a radio frequency (RF) electrode. The electrode may be configured to operate at a frequency of approximately 460 kHz. It is contemplated that any desired frequency in the RF range may be used, for example, from 450-500 kHz. It is further contemplated that ranges of frequency outside the RF spectrum may be used as desired, for example, but not limited to ultrasound, microwave, and laser.

FIG. **2** is an illustrative embodiment of a distal end of a renal nerve ablation system **12**. The system **12** may include an elongate shaft **21** having a distal end region **22**. The distal end region may be fixed to the elongate shaft **21** or may be movable longitudinally with respect thereto. The system **12** may include one or more strut assemblies **24** disposed radially about an inner expansion element **32**. The strut assemblies **24** may be attached to the shaft **21** at the proximal and distal ends of the strut assemblies or at only the proximal end of the strut assemblies or only at the distal ends of the strut assemblies. The strut assemblies may be disposed so they expand in a radially symmetric manner from the shaft. In other embodiments, the strut assemblies may expand asymmetrically from the shaft. There may be two, three, four (as shown), or more strut assemblies **24** and they may be spaced equally about the shaft **21** or may be spaced unequally. Each strut assembly **24** may include one, two (as shown) or more spacer struts **26** and an electrode strut **28**. An electrode **30** is attached to the electrode strut **28** and may be a separate piece joined to the electrode strut or may be formed with the electrode strut and the strut assembly from a single piece of material to form a monolithic electrode strut **28**/electrode **30** assembly. The conductive element(s) **16** are electrically connected to electrode(s) **30**. Each electrode may have a separate electrical connection through a conductive element **16** to the controller **18** or there may be a single conductive element **16** common to each electrode **30**. Each strut assembly **24** may form a portion of the conductive path to each electrode or a separate conductive path may extend between conductive element **16** and the electrode. Such a separate conductive path may be a separate wire or may be a conductive strip printed or otherwise formed on a strut assembly **24**.

The strut assemblies **24** can be collapsed to a low profile state by using, for example, the sheath **14** (other another suitable structure) and may be generally biased to an expanded state as shown. In other embodiments, the strut assemblies may be expanded outwardly using a balloon or other suitable mechanical means. In the expanded state, the spacer struts **26** extend out further radially than the electrode **30** and thus serve to keep the electrode a predetermined distance from the wall of a blood vessel when the system is in use. The inner expansion element **32** serves to partially occlude the vessel. It may, for example, expand to between 40% and 70% or to between 45% and 66% or to between 50% and 60% of the diameter of the system when the strut assemblies **24** are allowed to fully expand when unconstrained. The inner expansion element **32** may be a balloon that is inflated by injecting an inflation fluid through a connected lumen (not illustrated) or may be an expandable structure (like a stent-type structure, for example) covered by an impermeable membrane or by a substantially impermeable membrane. The membrane may be closed on both the proximal and distal ends or on either of the proximal and distal ends to substantially prevent blood flow through the stent to force the blood to flow only outside of the inner expansion element **32** to provide cooling to the electrodes **30**.

FIGS. **3**A and **3**B are a side view and an end view, respectively, of the system **12** introduced in a blood vessel and illustrate how the spacer struts **26** keep the electrodes spaced apart from the vessel wall **34**. These views also illustrate how the inner expansion element **32** serves to reduce the cross sectional area available for blood flow in the area of the electrodes **30**. The electrodes **30** are preferably kept spaced from the outer surface of the inner expansion element **32** as well as from the vessel wall **34**. In this embodiment, there are two spacer struts **26** for each electrode **30**, one spacer strut disposed on either side of the electrode. One feature of this arrangement is that it keeps the area between the electrode and the vessel wall free from intervening material. Other suitable arrangements of spacer struts are within the purview of this invention.

FIG. **4** is a side view of another illustrative embodiment of the distal portion of a renal nerve ablation system **12**. In this embodiment, the inner expansion member is omitted and the electrode struts are cantilevered, having a proximal end joined to the strut assembly and a free distal end (with the electrode thereupon). The distal end may terminate within the electrode or may extend distally beyond the electrode.

Features of the several illustrated embodiments may be readily combined with one another. For example, the cantilevered electrode struts of the FIG. **4** embodiment may be incorporated into the embodiment of FIG. **2**, which has the inner expansion member **32**.

FIG. **5** is a side view of another illustrative embodiment of the distal portion of a renal nerve ablation system **12**. In this embodiment, the electrodes are spaced apart longitudinally, with a first set **44** of two electrodes and their corresponding spacer struts spaced distally from a second set **46**. The inner expansion member **32** preferably extends under both sets. The inner expansion member **32** is shown as being formed as essentially one piece extending under both sets of electrodes. In other contemplated embodiment, the inner expansion member is formed from more than one lobe, such that there may be one lobe under the first set and a second lobe under the second set, with a narrower waist therebetween. In other contemplated embodiments, the system may include more than one expansion member. In other contemplated embodiments, each electrode **30** and that electrode's associated spacer struts **26** may be at a different longitudinal location. There may also be more than four electrodes (or fewer) or more than two sets of electrodes, as desired.

FIGS. **6**A, **6**B, **6**C and **6**D illustrate electrodes **36** integral with electrode struts **38**. "Integral with" in this context is intended to mean that the electrode and the electrode strut are both formed from the same precursor and can thus be said to be monolithic or of unitary construction. After the electrode and the strut are formed (by cutting a sheet or tube of material, for example), a strip of insulating material **40** may be applied around the perimeter of the electrode as illustrated in FIG. **6**B or the central portion of the electrode may be plated with a layer **42** of platinum or other suitable conductive and non-oxidizing material as illustrated in FIG. **6**C. Both the front surface and the back surface of the electrode may be plated with a layer **42**. "Plating" refers not only to plating but to any suitable process for depositing a suitable material. Electro-plating, laser deposition, printing are all contemplated. FIG. **6**D illustrates that in some instances it is desirable to have the insulating material **40** and the plating layer **42**.

FIG. **7** illustrates a non-integral electrode **30** disposed on a electrode strut **28**. The electrode may have a more rounded and three-dimensional ovoid shape when not formed from the same piece as the strut. Such an electrode may be made from a different material from the strut. For example, the strut may be made from nitinol and the electrode may be made from platinum.

FIGS. **8**A and **8**B are a side view and an end view, respectively, of a system **12**' (which may be similar to other systems disclosed herein) introduced in a blood vessel **34** and illustrate how one or more trip struts **27** may be incorporated into such a system. Trip struts **27** are placed between the vessel wall **34** and the electrodes **30**. In some cases, the trip strut **27** may be placed somewhat upstream from the electrode. FIG. **8**A illustrates two trip struts **27** in a strut assembly **24**, which allows the trips struts to be useful regardless of the direction of the blood flow. It is also contemplated that only one trip strut per electrode may be used. If, for example, the system is advanced into a renal artery as illustrated in FIG. **1**, only the distal trip strut **27** may be used. The location of the trip strut allows it to increase the turbulence in blood flow past the vessel wall under the electrode to increase heat transfer. The trip strut **27** is illustrative of other contemplated boundary layer control elements that may be used. Other suitable boundary layer control elements include bumps corners, expansions, surface roughness, trip wires, wings, fins, offset channels and the like. Such features may be attached to one or more of the struts of strut assemblies **24**, to the electrodes **30**, the inner expansion member **32** or to another suitable element of the system. For example, an expandable assembly incorporating such features may be attached to distal end region **22**. Some embodiments also include an active infusion system that may infuse a fluid such as a saline solution into the area to be treated. Such a system may improve cooling and also increase turbulence for improved heat transfer. An active infusion system can be added to a system that includes the boundary control elements such as the trip struts **27**.

Trip struts **27** are intended to increase heat transfer between a hot spot on the vessel wall caused by the ablation procedure and the fluid (usually blood) flow through the vessel by increasing the turbulence of the fluid flowing past the treatment location. Thus trip struts **27** are preferably placed somewhat upstream from the hot spot by placing them somewhat upstream of the electrode **30**. Trips struts **27** are also preferable extend in a direction that is substantially perpendicular to the blood flow. This direction may be a radial direction or may be (as shown in FIGS. **8**A and **8**B) a direction that is substantially perpendicular to a radius of the blood vessel. Struts **27** are also preferably not in contact with the blood vessel wall at the treatment location and thus are spaced away from the way and, in some instances, in an upstream direction from the treatment location.

The electrodes may be formed from any suitable material such as, but not limited to platinum, gold, stainless steel, cobalt alloys, or other non-oxidizing materials. In some instances, titanium, tantalum, or tungsten may be used. It is contemplated that the electrodes may take any shape desired, such as, but not limited to, square, rectangular, circular, oblong, etc. In some embodiments, the electrodes may have rounded edges in order to reduce the affects of sharp edges on current density. In some instances, the electrodes may have an aspect ratio of 2:1 (length to width).

FIG. **9** is an isometric view of the distal portions of an illustrative renal nerve modulation system **900** that apart from the components described with respect to FIG. **9** may be similar to other systems disclosed herein. System **900** comprises an expandable stent-like frame **902** that includes electrode pads **904**. Pads **904** are disposed on the frame **902** in a staggered pattern. A system **900** may include any desired number of pads **904**. Twelve pads **904** are shown in the figure but a lesser or greater number may be included. The pads are shown as circular but may be other shapes including, for example, ovals or oblongs. The frame **902** and the pads **904** are electrically conductive. Electrode pads **904** include a first side **906** that faces outwardly and contacts the wall of the blood vessel when expanded and a second side **908** that faces inward towards the center of the system **900**. The frame **902** and the electrode pad **904**, apart from the second side **908**, are covered with an electrically insulative material. Only the second side **908** of the pad **904** has an exposed conductive surface. Thus when the system **900** is expanded in a blood vessel the active portion of the electrode that transmits the RF energy will not be in contact with the vessel wall. Power is provided through a conductor **905** attached to the proximal end of the frame **902** and travels through the frame **902** to the pads **904**. This embodiment thus provides an alternative method of ablation using non-contact electrodes. In this embodiment, non-contact means that the active surface of the electrode is not in contract with the vessel wall. Preferably, frame **902** is self-expanding and thus is expanded when a catheter is proximally withdrawn relative to frame **902**.

Embodiments of system **900** are contemplated using alternative construction techniques. For example, any conventional self-expanding stent configuration may be appropriate for use as frame **902**. Pads **904** may be formed integral with the frame or formed separately and attached to the frame. If formed separately, the frame need not be the conductor. Separate conductors such as wires may provide power to the electrode pads. Pads **904** will have an insulative or non-conductive side which faces and makes contact with the vessel wall and an active side that faces away from the vessel wall.

It is contemplated that the systems described herein such as assembly **10**/system **12** or system **900** (and/or other assemblies/systems disclosed herein) may be operated in a variety of modes. In one embodiment, the assembly **10** may be operated in a sequential unipolar ablation mode. The electrodes may each be connected to an independent power supply such that each electrode may be operated separately and current may be maintained to each electrode. In sequential unipolar ablation, one electrode may be activated such that the current travels from the electrode to a ground electrode. After one electrode has been activated and then deactivated, another electrode may be activated such that current travels from that electrode to the ground electrode.

In another embodiment, the assembly **10** may be operated in a simultaneous unipolar ablation mode. In simultaneous unipolar ablation mode, the electrodes may be activated simultaneously such that current travels from each electrode to the ground electrode(s). In some instances, the electrodes may each be connected to an independent electrical supply such that current is maintained to each electrode. In this mode, more current may be dispersed radially. This may result in a more effective, deeper penetration compared to the sequential unipolar ablation mode.

In another embodiment, the assembly **10** may be operated in a bipolar mode. In this instance, two electrodes disposed at the treatment location may be 180° out of phase such that one electrode acts as the ground electrode (e.g. one cathode and one anode). As such current may flow around the elongate shaft from one electrode to the other electrode. In general, either sequential or simultaneous unipolar mode may penetrate more deeply than the bipolar mode. Any of the embodiments described herein may be operated in any of the above described modes.

In use, a system **12** may introduced percutaneously as is conventional in the intravascular medical device arts. For example, a guide wire may be introduced percutaneously through a femoral artery and navigated to a renal artery using standard radiographic techniques. A guide catheter may be introduced over the guide wire and the guide wire is withdrawn. The system **12** may be introduced into the guide catheter with the strut assemblies **24** compressed within the sheath **14**. Alternatively, the sheath **14** may take the form of a guide catheter. Once the distal end of the system **12** is at the desired location within the renal artery, the sheath **14** may be withdrawn to allow the strut assemblies **24** to expand. If inner expansion element **32** is present, it may be expanded or allowed to expand to partially restrict the flow of blood through the treatment site. The electrodes **30** are activated to ablate nerve tissue. The sheath **14** may then be advanced over the system **12** to compress the strut assemblies **24** and then the sheath **14** and system **12** may be withdrawn out of the patient's body.

The system may be manufactured using the following technique. The strut assemblies **24** for a system **12** may be formed from a single tubular member. The tubular member may be cut to form the strut assemblies **25** including the spacer struts **26**, the electrode struts **28** and, in certain embodiments, the electrodes **30**. At this stage, however, the strut assemblies **24** are still joined to each other by tubular proximal and/or distal rings. The strut assemblies are then shaped and then the cut and shaped tubular member is slid over a shaft **21** and the proximal and/or distal ends of the strut assemblies are joined to the shaft **21**. At this point, the proximal and distal rings are cut off and removed to separate the strut assemblies from each other. Another layer may be slid over the proximal and/or distal ends of the strut assemblies to further secure the strut assembly to the shaft. For example, a heat shrink tube may be used as the additional layer at the proximal and distal ends of the strut assembly.

Those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departure in form and detail may be made without departing from the scope and spirit of the present invention as described in the appended claims.

What is claimed is:

**1**. A system for nerve modulation through a wall of a blood vessel, comprising:

an elongate member extending along a central elongate axis and having a proximal end and a distal end, the elongate member having a radially expandable member disposed proximate the distal end; and

a tubular sheath cooperatively engaged with the expandable member such that the expandable member is not expanded when in the tubular sheath and can expand when moved out of the tubular sheath,

the expandable member comprising a plurality of electrodes on an expandable frame wherein each of the plurality of electrodes has a first surface that is entirely electrically insulated and faces radially outwards relative to the expandable member and a second surface that is electrically conductive surface that and faces radially inwards towards a central longitudinal axis of the expandable member.

**2**. The system of claim **1**, wherein the expandable frame provides a conductive path to the plurality of electrodes and wherein the expandable frame is electrically insulated.

**3**. The system of claim **1**, wherein the expandable member is self-expanding.

**4**. The system of claim **1**, wherein at least some of the plurality of electrodes and the expandable frame are formed from the same material.

**5**. The system of claim **1**, wherein the plurality of electrodes are disposed on the expandable frame in an axially and circumferentially staggered pattern.

**6**. The system of claim **1**, wherein the expandable frame and the first surface of each of the plurality of electrodes is covered with an electrically insulative material.

**7**. The system of claim **1**, wherein the expandable frame extends to the proximal end of the elongate member.

**8**. The system of claim **1**, wherein the plurality of electrodes are each connected to an independent power supply.

**9**. A system for nerve modulation through a wall of a blood vessel, comprising:

an elongate member extending along a central elongate axis and having a proximal end and a distal end, the elongate member having a radially expandable member disposed proximate the distal end; and

a tubular sheath cooperatively engaged with the expandable member such that the expandable member is not expanded when in the tubular sheath and can expand when moved out of the tubular sheath,

the expandable member comprising a plurality of non-contact electrodes on an expandable frame, wherein each of the plurality of non-contact electrodes has a single electrically conductive surface, wherein the expandable member is configured such that when the expandable frame is expanded and in contact with a blood vessel wall, the electrically conductive surface of each of the plurality of non-contact electrodes does not contact the blood vessel wall and faces radially inward towards a central longitudinal axis of the expandable member.

**10**. The system of claim **9**, wherein the expandable frame is non-conductive, and conductor wires connect the plurality of non-contact electrodes to a conductor attached to the proximal end of the expandable frame.

**11**. The system of claim **9**, wherein the expandable member is self-expanding.

**12**. The system of claim **9**, wherein at least some of the plurality of non-contact electrodes and the expandable frame are formed from the same material.

**13**. The system of claim **9**, wherein the plurality of non-contact electrodes are disposed on the expandable frame in an axially and circumferentially staggered pattern.

**14**. The system of claim **9**, wherein the plurality of non-contact electrodes are each connected to an independent power supply.

**15**. A system for nerve modulation through a wall of a blood vessel, comprising:

an elongate member extending along a central elongate axis and having a proximal end and a distal end, the elongate member having a radially expandable member disposed proximate the distal end; and

a tubular sheath cooperatively engaged with the expandable member such that the expandable member is not expanded when in the tubular sheath and can expand when moved out of the tubular sheath,

the expandable member comprising an expandable frame having a plurality of widened regions axially and circumferentially staggered along the expandable frame, wherein each of the plurality of widened regions has a first completely electrically insulated surface that faces radially outwards relative to the expandable member and a second electrically conductive surface that faces radially inwards towards a central longitudinal axis of the expandable member.

**16**. The system of claim **15**, wherein the expandable frame is non-conductive, and conductor wires connect the plurality of widened regions to a conductor attached to the proximal end of the expandable frame.

**17**. The system of claim **15**, wherein the expandable member is self-expanding.

**18**. The system of claim **15**, wherein the plurality of widened regions are each connected to an independent power supply.

**19**. The system of claim **15**, wherein the expandable frame extends to the proximal end of the elongate member.

**20**. The system of claim **15**, wherein the expandable frame provides a conductive path to the plurality of widened regions and wherein the expandable frame is electrically insulated.

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